510(k) SUMMARY

JUN 30 2014

1.0 Submitter:

Name: Mr. Francis V
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Malaysia.
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Date of Summary Prepared: June 27, 2014

2.0 Name of the device:

Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile

Common Name: Patient Examination Glove

Classification Name: Patient Examination Gloves (21 CFR 880.6250 product code LZA)

Regulatory Class I

3.0 Identification of The Legally Marketed Devices that equivalency is claimed:

Dermagrip Ultra Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile (and various brandnames)
510(k) : K110979
MDL : D133849
Regulatory Class I
Product Code : LZA

4.0 Description of The Device:

Predicate K110979	Current K132354
Dermagrip Ultra Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile (and various brandnames) meets all the requirements of ASTM standard D6319-10 and FDA 21 CFR 880.6250.	Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile meets all the requirements of ASTM standard D6319-10 and FDA 21 CFR 880.6250. The powder free nitrile examination glove is manufactured from synthetic rubber latex. Inner surface of gloves undergo surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is ambidextrous; i.e. can be worn on right hand or left hand.

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5.0 Intended Use of the Device:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate K110979	Current K132354
Dimensions	ASTM D6319-10	Meets	Meets Length min 230mm Width min 95±10
Physical Properties	ASTM D6319-10	Meets	Meets **Before Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 400%
Thickness	ASTM D6319-10	Meets	Meets Finger min 0.05mm Palm min 0.05mm
Powder Free	ASTM D6124-06 (Reapproved 2011)	Meets ≤ 2 mg/glove	Meets ≤ 2 mg/glove

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CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate K110979	**Current K132354**
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010(E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500	Passes (Not a primary skin irritant) There was no erythema or oedema noted on abraded or non-abraded sites at 24±1 hours and 72±1 hours. The Primary Irritation Index (PII) of test material was "0".	Passes (Not a primary skin irritant) There was no erythema or oedema noted on abraded or non-abraded sites at 24±1 hours and 72±1 hours. The Primary Irritation Index (PII) of test material was "0".
	Dermal Sensitization - ISO 10993-10:2010(E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500.3(c)(4)	Passes (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 0±2, 24±2 hours and 48±2 hours) in animals treated with the test material and negative control.	Passes (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 0±2, 24±2 hours and 48±2 hours) in animals treated with the test material and negative control.
Watertight (1000ml)	ASTM D5151-06 (Reapproved 2011)	Passes	Passes AQL 2.5
Intended Use	-	The powder free examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste or environment.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate K110979	Current K132354
Material	ASTM D6319-10	Nitrile	Nitrile Sulphur Zinc Oxide Zinc Dibutyldithiocarbamate (ZDBC) Zinc Diethyldithiocarbamate (ZDEC) Phenolic Antioxidant Titanium Dioxide Blue Pigment
Color	-	Blue	Blue
Texture	-	Finger textured	Finger textured
Size	Medical Glove Guidance Manual – Labeling	Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Glove Guidance Manual – Labeling	Single use	Single use
Manufacturer(s)	-	Advance Medical Products Sdn Bhd	Advanced Healthcare Products Sdn Bhd

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

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9.0 Conclusion

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.
Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile will perform according to the gloves performance standards such as ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, the device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

Advanced Healthcare Products Sdn Bhd
Mr. Francis V
Operations Manager
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70450 Seremban, Negeri Sembilan
Darul Khusus, MALAYSIA

Re: K132354
Trade/Device Name: Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: May 20, 2014
Received: May 22, 2014

Dear Mr. Francis V:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132354

Device Name
Powder Free Blue Nitrile Patient Examination Glove Non-Sterile

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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